

PATENT COOPERATION TREATY

PCT

REC'D 20 MAY 2005

INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference P60659PC00 | FOR FURTHER ACTION | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |
| International application No. PCT/NL 03/00741 | International filing date (day/month/year) 30.10.2003 | Priority date (day/month/year) 25.03.2003 |
| International Patent Classification (IPC) or both national classification and IPC G01N33/68 | | |
| Applicant STICHTING SANQUIN BLOEDVOORZIENING et al. | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I Basis of the opinion
- II Priority
- III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV Lack of unity of invention
- V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI Certain documents cited
- VII Certain defects in the international application
- VIII Certain observations on the international application

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|--|---|
| Date of submission of the demand 07.10.2004 | Date of completion of this report 19.05.2005 |
| Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | Authorized Officer Moreno de Vega, C Telephone No. +49 89 2399-7486 |



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/NL 03/00741

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed"* and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)):

Description, Pages

1-14 as originally filed

Claims, Numbers

1-30 as originally filed

Drawings, Sheets

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
 the language of publication of the international application (under Rule 48.3(b)).
 the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- contained in the international application in written form.
 filed together with the international application in computer readable form.
 furnished subsequently to this Authority in written form.
 furnished subsequently to this Authority in computer readable form.
 The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
 The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
 the claims, Nos.:
 the drawings, sheets:

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5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).
(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)
6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|------|
| Novelty (N) | Yes: Claims | 1-30 |
| | No: Claims | |
| Inventive step (IS) | Yes: Claims | 1-30 |
| | No: Claims | |
| Industrial applicability (IA) | Yes: Claims | 1-30 |
| | No: Claims | |

2. Citations and explanations

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/NL 03/00741

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Article 33(2) and (3) PCT

Present claims 1-30 are considered to be novel. The known prior art documents do not disclose the method for detection of a pathogenic form of a prion protein of said claims.

The technical problem to be solved by present claims 1-30 is the provision of a diagnostic method which allows a sensitive and reliable quantification of PrP^{Sc} in a sample. The solution is based in the use of a microtitre plate with an enhanced binding of the pathogenic or scrapie form as compared to a normal microtitre plate, i.e. an ELISA with a chemically modified transparent microtitre plate, namely a clear nitrocellulose layer on the bottom of wells of a regular microtitre plate. This solution is not suggested in the known prior art documents, taken alone or in combination. Thus, claims 1-30 are considered to be inventive.

Present claims 1-30 meet therefore the requirements of Article 33(2) and (3) PCT.

2. Article 6 PCT

It is clear from the description on page 4 that the following feature is essential to the definition of the invention:

The chemical modification of the microtitre plate comprises an application of a clear nitrocellulose layer or a clear layer of other suitable cellulose derivatives on the bottom of wells of a regular microtitre plate.

Since independent claims 1 and 25 do not contain this feature they do not meet the requirement following from Article 6 PCT taken in combination with Rule 6.3(b) PCT that any independent claim must contain all the technical features essential to the definition of the invention.

**INTERNATIONAL PRELIMINARY
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International application No. PCT/NL 03/00741